

PATENT COOPERATION TREATY

REC'D 04 JUL 2005
WIPO PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:
W. THAD ADAMS III
ADAMS EVANS P.A.
2180 TWO WACHOVIA CENTER
CHARLOTTE, NC 28282

Date of mailing **30 JUN 2005**
(day/month/year)
FOR FURTHER ACTION
See paragraph 2 below

Applicant's or agent's file reference

2765/251PCT

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US05/04454

14 February 2005 (14.02.2005)

31 March 2004 (31.03.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61F 5/00 and US Cl.: 602/8

Applicant

BSN MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Kim M. Lewis

Telephone No. (571) 272-4395

Form PCT/ISA/237 (cover sheet) (January 2004)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/04454

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____ which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US05/04454

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>8 and 13</u>	YES
	Claims <u>1-7 and 9-12</u>	NO
Inventive step (IS)	Claims <u>8 and 13</u>	YES
	Claims <u>1-7 and 9-12</u>	NO
Industrial applicability (IA)	Claims <u>1-13</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-13 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent No. 6,488,642 ("Darcey") in view of U.S. Patent No. 6,280,815 ("Ersfeld et al").

Regarding claims 1, 3, 5, 9 and 10, Darcey substantially discloses all the claimed features. More specifically, Darcey discloses, a medical bandaging product in roll form for being dispensed in predetermined lengths suitable for a given medical use, and comprising an elongate sleeve formed of moisture-impervious material and sealable to prevent entry of moisture until use, the medical bandage material substantially the same length as the sleeve and sealed therein against entry of moisture until use, the medical bandage material comprising, a substrate (16), a reactive system impregnated into or coated onto the substrate and remaining stable when maintained in substantially moisture-free conditions and hardening upon exposure to sufficient moisture to form a rigid, self support structure (col. 8, lines 21-25). Darcey also discloses padding (tubular wrapping 18 at col. 7, lines 26-33) and resealing means for resealing the sleeve against entry of moisture after a predetermined length of the bandage material has been dispensed from the sleeve for use to prevent hardening of the substrate of the bandage material remaining in the sleeve (col. 8, lines 21-25).

Darcey fails to teach that the substrate comprises a foam layer, that the foam is polymer foam and that the substrate includes a textile reinforcement layer. However, Ersfeld et al. disclose a substrate comprising a polymer foam (52) and textile reinforcement layers (54, 56). The foam is impregnated with a hardenable (setting) resin as a means by which a custom shoe insert is made.

In view of Ersfeld et al., it would have been obvious to one having ordinary skill in the art to substitute the materials of construction for substrate (16) of Darcey for the materials of construction of substrate (50) of Ersfeld et al. as an obvious alternative since it appears that both substrates perform the same function.

Regarding claim 2, note col. 8, lines 9-14.

Regarding claim 4, note the table in col. 7, which discloses the formulation of the reaction system

Regarding claim 6, note Fig. 14 and col. 5, line 60-col. 6, line 14.

Regarding claim 7, note dispenser (11).

Regarding claim 11, the method as claimed is inherently practiced when the modified device of Darcey (see the discussion of claim 1 above).

Regarding claim 12, Darcey discloses a package comprising an elongate sleeve (13) and the medical material is generally the same length as the sleeve. Further, disclosed in the inherent step of positioning the bandage material within the package comprises the step of placing the bandage material within the sleeve such that the bandage material extends along the length of the sleeve in a single layer (Fig. 1).

Claims 8 and 13 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest that some of the fibers from the textile reinforcement layer penetrate into the foam layer for providing rigidity and stability.

Claims 1-13 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

**WRITTEN OPINION OF THE
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International application No.

PCT/US05/04454

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: Page 8, para. [0036], line 4, "14" should read -13-.

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